

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.

#### Protocol summary

##### Study aim

Comparison of muscle relaxant dose of cis-atracurium based on body fat mass, total body weight, and ideal body weight, in patients undergoing obesity surgery.

##### Design

The present study is a single-blind clinical trial conducted on 60 obese patients who are candidates for bariatric surgery referring to Firoozgar Medical Center (from 96 to 98). Randomization is done using identical envelopes. These envelopes are provided to patients, based on the envelopes they have selected in one of three study groups (FFM-TBW - IBW), which according to inclusion and exclusion criteria, eventually 60 The plan is selected.

##### Settings and conduct

This study is performed on patients undergoing obesity surgery referred to Firoozgar Hospital during the years 1396-1399. The amount of muscle relaxant required in these three groups with TOF monitoring during surgery, need to be repeated repeatedly. The TOF is monitored during surgery. The comparison of the duration of the patient's muscle relaxation after cis-atracurium infusion was discontinued in the three study groups. Time to reach TOF 4, comparison of amount of rivers consumed in the three study groups, comparison of time interval between rivers administration to appropriate conditions for acquisition in three groups, length of time to reach TOF 4 after rivers injection and surgeon satisfaction from field Diaphragm operation and relaxation are measured and recorded.

##### Participants/Inclusion and exclusion criteria

Ages 18 to 60 , BMI greater than 35 kg / m<sup>2</sup>. Pregnancy ,Neuromuscular Disease, Treatment with Well-known Interventions in Muscle Neurotransmission. Psychological Disorder, Allergy to Cis-atracurium,

##### Intervention groups

Our intervention is cisatracurium, which is injected according to study objectives into three groups: body fat

mass, total body weight and ideal body weight .

##### Main outcome variables

Duration of anaesthesia, Time of TOF, quality of intubation,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151107024909N9**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

##### Registration date

2020-03-11, 1398/12/21

##### Registrant information

##### Name

Faranak Rokhtabnak

##### Name of organization / entity

Iran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8894 6267

##### Email address

rolhtabnak.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-29, 1398/11/09

##### Expected recruitment end date

2020-04-19, 1399/01/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.

**Public title**

Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ages 18 to 60 Patients with physical level below 3 according to the American Society of Anesthesiologists classification BMI greater than 235 kg / m Normal kidney and liver function confirmed by routine screening tests

**Exclusion criteria:**

Pregnancy , Neuromuscular Disease Treatment with Well-known Interventions in Muscle Neurotransmission Psychological Disorder Allergy to Cis-atracurium Criteria for Difficult Intubation

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done using identical envelopes, each envelope containing the name of one of the groups under study. These envelopes are available to patients who are candidates for bariatric surgery. They fall into one of three study groups (FFM - TBW - IBW) based on their envelope. According to the inclusion and exclusion criteria, 60 patients were finally selected for the study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients are divided into study groups using the same prepared envelopes and none of the patients are aware of the assigned group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

No. 14 , Dejamjo Ave., Kamranieh Town

**City**

Tehran

**Province**

Tehran

**Postal code**

553406080050

**Approval date**

2020-01-21, 1398/11/01

**Ethics committee reference number**

IR.IUMS.FMD.REC.1398.465

**Health conditions studied****1****Description of health condition studied**

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

Duration of muscle relaxation

**Timepoint**

During surgery

**Method of measurement**

Minutes

**2****Description**

Dose of Cisatracurium

**Timepoint**

During surgery

**Method of measurement**

Mg, syringe

## Secondary outcomes

### 1

#### Description

Need for antagonism

#### Timepoint

During surgery and after surgery

#### Method of measurement

Mg, syringe

## Intervention groups

### 1

#### Description

Intervention group1: In the first group, the dose of cisatracurium was injected based on body fat mass (FFM) and changed during the dose of the drug based on the patient's hemodynamic status. It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cisatracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group2: In the second group, the dose of cisatracurium is injected based on total body weight (TBW) and changes in the dose of the drug are based on the patient's hemodynamic status during surgery. It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cisatracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: In the third group, the dose of cisatracurium is injected based on ideal body weight (IBW) and changes in the dose of the drug are based on the patient's hemodynamic status during surgery. It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cisatracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firoozgar hospital

##### Full name of responsible person

Faranak Rokhtabnak

##### Street address

No. 14 , Dejamjo Ave., Kamranieh Town

##### City

Tehran

##### Province

Tehran

##### Postal code

553406080050

##### Phone

+98 21 8871 7272

##### Email

Rolhtabnak.f@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Sied Abass Motavaliian

##### Street address

Floor 5- Iran University of Medical Sciences-next to Milad Tower- Hemat High Way

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 2503

##### Fax

+98 21 8862 2307

##### Email

research-m@iums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Phone**

+98 21 8871 7272

**Email**

rolhtabnak.f@iums.ac.ir

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Faranak Rokhtabnak

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available